

This is an official
CDC Health Advisory

Distributed via Health Alert Network
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**Manufacturer's Recall of Nasal Spray Contaminated with
Burkholderia cepacia Complex**

Clinicians should be aware that the Centers for Disease Control and Prevention (CDC) has been notified of a voluntary recall of over-the-counter oxymetazoline HCL 0.05% nasal spray because of intrinsic contamination with *B. cepacia* complex. Patients with underlying lung disease (especially cystic fibrosis) may be at increased risk for severe infections with *B. cepacia* complex.

The manufacturer, Propharma Inc., has recalled lot# K4496 released 11/03 with an expiration date of 10/06. Preliminary molecular epidemiology indicates that isolates related to the strain found in the nasal spray have been recovered from patients in multiple states.

CDC is assisting the state of Missouri, investigating several cases of *B. cepacia* that have been identified in one hospital, to examine the impact of the recalled product on patient safety and the potential spread of *B. cepacia* within the healthcare setting.

Disease symptoms and characteristics

B. cepacia is a multidrug-resistant organism and management of patients with these bacteria should be in accordance with hospital policy for infection control and isolation precautions. *B. cepacia* poses very little medical risks to healthy people; however, people whose health is otherwise compromised may be more susceptible. If individuals have used this product and are concerned they should contact their healthcare provider.

B. cepacia consists of several species, or a complex, of bacteria, that are found in the natural environment. Some of these species threaten the health of individuals with cystic fibrosis (CF). It is important to note that in general, the species that colonize the lungs of people with CF differ from most of those found in the natural environment. However, all species of *B. cepacia* have been recovered from the sputum of people with CF; these bacteria were only first reported in people with CF in the 1970s.

B. cepacia bacteria are able to survive in the environment or in the lungs of a person with CF. They are resistant to most common cleaning disinfectants and to many antibiotics, which makes them difficult to treat once they infect the lungs. However, some species may be successfully treated with combinations of antibiotics. Standard health precautions greatly reduce the risk of infection.

DHEC Contact Information for Reportable Diseases and Reporting Requirements

Healthcare providers and laboratory staff should report suspect and confirmed cases of *B. cepacia* complex infection or colonization associated with use of this product to their local and State health departments. State Health Departments will report cases to the CDC.

Reporting of cases is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2004 List of Reportable Conditions available at:
<http://www.scdhec.net/hs/diseasecont/disease.htm>.

The following is a complete listing of both local and state numbers for use in reporting **ANY** disease or condition.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512)

District Public Health Offices

Mail or call reports to the District Epidemiology/Disease Reports office in each district.

Appalachia I

(Anderson, Oconee)
220 McGee Road
Anderson, SC 29625
Phone: (864) 231-1966
Fax: (864) 260-5623
Nights / Weekends: 1-866-298-4442

Appalachia II

(Greenville, Pickens)
PO Box 2507
200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 282-4139
Fax: (864) 282-4373
Nights / Weekends: (864) 460-5355 or
1-800-993-1186

Appalachia III

(Cherokee, Spartanburg, Union)
PO Box 4217
151 E. Wood Street
Spartanburg, SC 29305-4217
Phone: (864) 596-2227 ext. 210
Fax: (864) 596-3443
Nights / Weekends: (864) 809-3825

Catawba

(Chester, Lancaster, York)
PO Box 817
1833 Pageland Highway
Lancaster, SC 29721
Phone: (803) 283-3175
Fax: (803) 283-0572
Nights / Weekends: 1-866-867-3886 or
1-888-739-0748

Edisto Savannah

(Aiken, Allendale, Barnwell)
1680 Richland Avenue, W. Suite 40
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 642-1619
Nights / Weekends: (803) 827-8668 or
1-800-614-1519

Edisto Savannah

(Bamberg, Calhoun, Orangeburg)
PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 533-7199
Fax: (803) 536-9118
Nights / Weekends: (803) 954-8513

Low Country

(Beaufort, Colleton, Hampton, Jasper)
1407 King Street
Beaufort, SC 29902
Phone: (843) 525-7603
Fax: (843) 525-7621
Nights / Weekends: 1-800-712-6586

Palmetto

(Fairfield, Lexington, Newberry, Richland)
2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: (803) 304-4252

Pee Dee

(Chesterfield, Darlington, Dillon,
Florence, Marlboro, Marion)
145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 660-8145

Trident

(Berkeley, Charleston, Dorchester)
4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 746-3832
Fax: (843) 746-3851
Nights / Weekends: (843) 219-8470

Upper Savannah

(Abbeville, Edgefield, Greenwood,
Laurens, McCormick, Saluda)
PO Box 3227
1736 S. Main Street
Greenwood, SC 29646
Phone: 1-888-218-5475
Fax: (864) 942-3690
Nights / Weekends: 1-800-420-1915

Waccamaw

(Georgetown, Horry, Williamsburg)
2830 Oak Street
Conway, SC 29526-4560
Phone: (843) 365-3126
Fax: (843) 365-3153
Nights / Weekends: (843) 381-6710

Wateree

(Clarendon, Kershaw, Lee, Sumter)
PO Box 1628
105 North Magnolia Street
Sumter, SC 29150
Phone: (803) 773-5511
Fax: (803) 773-6366
Nights / Weekends: 1-877-831-4647

Bureau of Disease Control

Acute Disease Epidemiology Division
1751 Calhoun Street
Box 101106
Columbia, SC
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action.

Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.